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October 11, 2006

Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1321-P
Box 8015
Baltimore, Maryland 21244-8015

RE: file code CMS-1321-P

Dear Dr. McClellan:

The Medicare Payment Advisory Commission (MedPAC) is pleased to submit these comments on CMS's proposed rule entitled: *Medicare program; Revisions to payment policies under the physician fee schedule for calendar year 2007 and other changes to payment under Part B* [CMS-1321-P] Federal Register, August 22, 2006. We appreciate your staff's ongoing efforts to administer and improve the payment system for physicians' services, particularly considering the agency's competing demands.

Deficit Reduction Act of 2005 (DRA) proposals

Section 5102 – Proposed adjustments for payments to imaging services

In the physician fee schedule final rule for 2006, CMS adopted a policy to reduce the technical component payment for multiple diagnostic imaging services when they are performed on contiguous body parts during the same session. We recommended this policy in our March 2005 Report to the Congress because there are cost efficiencies when multiple studies of the same modality are performed on contiguous areas. CMS initially proposed a 50 percent reduction for subsequent imaging services when providers furnish more than one service from the same family of codes (e.g., computed tomography of the spine). CMS justified a 50 percent reduction based on an analysis of the clinical activities that are not duplicated for subsequent procedures, such as positioning and escorting the patient, providing education and obtaining consent, and preparing and cleaning the room. In addition, CMS assumed that supplies, with the exception of film, are not duplicated. Removing the costs of the activities and supplies that are not duplicated supported a payment reduction ranging from 40 to 59 percent for the additional services; the midpoint of this range was 50 percent. To allow for a transition, CMS decided in the final rule to phase in this reduction over two years by implementing a 25 percent reduction in 2006 and

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Mark McClellan
Administrator
Page 2

planning to adopt a 50 percent reduction in 2007, subject to additional review. CMS also solicited data from providers on the efficiencies associated with different combinations of imaging studies.

In this proposed rule, CMS proposes to maintain the current 25 percent reduction for 2007 for two reasons:

- The interaction between this policy and a provision from the Deficit Reduction Act of 2005 (DRA) that caps the physician fee schedule technical component (TC) rate for an imaging service at the outpatient prospective payment system (OPPS) rate, and
- Data submitted by the American College of Radiology (ACR) for 25 common combinations of services that supports a reduction between 21 and 44 percent.

It is unclear why the DRA provision that caps the physician fee schedule TC rate at the OPPS rate justifies maintaining the 25 percent reduction for 2007 for all imaging services, rather than implementing a 50 percent reduction. The DRA policy does not apply to all imaging services, only to those for which the TC rate exceeds the OPPS rate.

In the final rule, we ask that CMS provide more information on the ACR cost data on multiple imaging services cited in the proposed rule. Are the data based on a physician survey or an analysis of practice expense inputs? If the data are from a survey, how representative was the survey and what questions were asked? Which combinations of codes did the ACR examine? What were the cost savings for each combination? How did the ACR's estimated cost savings compare to CMS's estimated savings (published in last year's final rule) for the same combinations of services? Given the lack of detailed information in the proposed rule, we are not convinced that the ACR data justify maintaining a 25 percent reduction for 2007.

Section 5107 – Revisions to payments for therapy services

The proposed rule notes that CMS is considering coding edits for therapy services in addition to the edits it implemented in 2006. The DRA required that clinically appropriate edits, including edits of clinically illogical combinations, for therapy services be implemented by July 2006. To comply with this requirement, CMS implemented the correct coding initiative (CCI) edits in all facility-based providers in January 2006. CMS also notified providers that it would implement additional edits in January 2007 to limit the number of untimed services that can be billed on the same day for one beneficiary.

The edits that CMS has implemented represent a good start in controlling inappropriate billings. We encourage further work and consultation with experts in areas such as utilization management and appropriateness of therapy services to develop clinically appropriate edits for timed services. Edits for timed services are especially important because they represent the majority of therapy services. Edits could limit the number of

Mark McClellan
Administrator
Page 3

timed units based on the amount of therapy that is typically tolerated by an elderly person. Other edits might target certain combinations of services that do not make clinical sense.

ASP Issues

In 2005, Medicare began paying for Part B drugs using the average sales price (ASP) methodology. In the first quarters of 2005, the new payment system produced dramatic price decreases for many products as Medicare payment rates began to approach the prices providers paid. By 2006, payment rates were more stable. In cases where generic products became available or branded drugs competed for market share, the payment rate has continued to decline. In other cases, payment rates are slowly increasing but, to date, less than other outpatient drug prices.

The Congress directed the Commission to conduct two studies on the effect of the changes in the payment rate. For these studies, we have conducted interviews with physicians, hospital administrators, wholesalers, manufacturers, and other stakeholders. Most physicians have told us that they can buy most drugs at the Medicare payment level but all report they cannot purchase some drugs at that payment rate. Interviewees talked about two issues: the gap between the average payments received by manufacturers and the average prices physicians pay when the calculation of ASP includes discounts that are not passed on to physicians, and how discounts are allocated in the calculation of ASP when drugs produced by one manufacturer are sold in a bundle.

The Commission encourages the Secretary to look into these issues and we intend to examine them further in the coming months as part of our mandated study. Although not perfect, the Commission views ASP as a vast improvement over the former payment method based on AWP. The objective of the ASP system should be to achieve accurate prices without creating inflationary incentives. Regarding the case of bundled discounts, the Commission is concerned about this issue and will be exploring whether to change the ASP calculation rules on how discounts are allocated between two drugs if a higher discount is provided when they are purchased together.

Finally, to ensure the accuracy of Medicare payments, the Secretary should monitor the acquisition costs of all providers who the Secretary pays under the ASP payment system, including physicians and dialysis providers. In this regulation, the Secretary is extending the 2006 payment policy of ASP plus 6 percent for separately billable drugs furnished by dialysis providers through 2007 and subsequent years. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required that the payment rates for dialysis drugs approximate the costs that dialysis providers incur.

The Secretary initially set the payment rate for physicians and dialysis providers at ASP plus 6 percent to account for the variation in their acquisition costs. However, there is no recent evidence that this payment rate reflects the variation in the acquisition costs of physicians and dialysis providers so the Secretary should not set the payment rate indefinitely. In our June 2005 Report to the Congress, the Commission recommended that

Mark McClellan
Administrator
Page 4

the Secretary periodically collect acquisition cost data from dialysis providers and compare it to ASP data. Analysis could lead to a resetting of the rate at a different percentage.

ESRD provisions

CMS proposes a new method to annually calculate the growth update to the add-on payment to the composite rate (as mandated by the MMA). Using this new method, the agency proposes to update the add-on payment by 0.6 percent, thus increasing the total add-on payment from 14.5 percent in 2006 to 15.2 percent in 2007.

In our June 2005 report, the Commission recommended combining these two payments. The add-on payment is complex and administratively burdensome for the agency to maintain. Increasing the add-on payment to post-MMA spending for dialysis drugs risks overpayment for use of the drugs. For these reasons, the Secretary should seek Congressional authority to combine the composite rate and the add-on payment.

Reassignment and physician self-referral

CMS proposes changes to the reassignment and physician self-referral rules designed to eliminate “pod labs” for pathology services. In a pod lab arrangement, an entity leases an office building, subdivides it into separate cubicles, equips each space with laboratory equipment, and hires staff to perform the technical and professional components of pathology tests. The entity then subleases each cubicle to a physician group practice, which may be located far away. The group practice sends its specimens to this lab and pays the entity a fee to perform the pathology tests. The practice then bills Medicare for the services, typically at a markup from the fee it has paid the management entity. Some commenters alleged that these arrangements lead to the generation of unnecessary biopsies, kickbacks, and referrals that would otherwise be prohibited by the physician self-referral statute.

CMS proposes to prohibit pod lab arrangements by amending the reassignment provision, under which a physician may bill for a service performed by another provider. CMS also proposes to limit the in-office ancillary exception under the physician self-referral law. We support policies to restrict arrangements between physicians and other entities that create financial incentives for inappropriate use of services.

IDTF issues

In response to concerns about fraud and abuse involving independent diagnostic testing facilities (IDTFs), CMS proposes to establish 14 new standards for IDTFs to ensure that they follow good business practices and provide quality care. IDTFs are entities— independent of a hospital or physician office—in which nonphysician personnel furnish diagnostic procedures under physician supervision. Medicare requires that IDTFs meet minimum standards for staff qualifications, equipment, and the supervising physicians.

Mark McClellan
Administrator
Page 5

Carriers must verify through a site visit and document review that IDTFs meet these standards when they enroll in Medicare but are usually not required to perform follow-up monitoring. A recent report by the Office of Inspector General (OIG) found that many Medicare payments to IDTFs were improper due to poor documentation or lack of medical necessity (Office of Inspector General, Review of claims billed by independent diagnostic testing facilities for services provided to Medicare beneficiaries during calendar year 2001, June 2006). OIG also learned that IDTFs did not always comply with their initial enrollment applications and update requirements (IDTFs are required to inform carriers when they begin to furnish new types of services or change their supervising physicians). OIG recommended that CMS consider performing site visits to monitor compliance with IDTFs' enrollment applications and subsequent updates should funding become available. In response, CMS stated that it lacked the funds to require Medicare carriers to conduct site visits to monitor IDTF compliance and that it instead planned to propose business standards for these providers.

The IDTF business standards proposed by CMS are modeled on Medicare's standards for durable medical equipment suppliers. Examples of the requirements include:

- Maintaining a comprehensive liability insurance policy
- Agreeing to not directly solicit patients
- Maintaining a primary phone number and address
- Using testing equipment that is calibrated per equipment instructions and in compliance with national standards
- Ensuring that technical staff with appropriate credentials are on duty.

In our March 2005 Report to the Congress, we described rapid growth in imaging services paid under the physician fee schedule, quality problems with at least some imaging providers, and the lack of quality oversight for imaging tests provided in non-hospital settings. Consequently, the Commission recommended that the Congress direct the Secretary to set quality standards for providers who bill Medicare for performing and/or interpreting diagnostic imaging studies. We also recommended that, to reduce the burden on CMS, the Secretary should select private sector organizations to administer the standards. We encouraged CMS to set standards in at least the following areas: the imaging equipment, qualification of technicians, qualifications and responsibilities of the supervising and interpreting physicians, quality of the images produced, and patient safety procedures.

Our recommendations apply to imaging providers in all settings, but we encourage CMS to move forward with strengthening quality standards for IDTFs. About 85 percent of Medicare payments for IDTFs in 2002 were for imaging services (MedPAC, A data book: Healthcare spending and the Medicare program, June 2004). We support CMS's proposal to improve IDTF standards related to testing equipment and technical staff, and we urge the agency to go further by adopting standards for image quality, patient safety procedures, and the qualifications of physicians who interpret studies performed in IDTFs

Mark McClellan
Administrator
Page 6

(the professional component). CMS should also explore opportunities to set quality standards for imaging services performed in physician offices. To the extent necessary, CMS should pursue statutory authority to adopt such standards. We recognize that CMS has limited resources to enforce IDTF standards. Thus, the agency should consider authorizing private accreditation organizations to verify that IDTFs meet CMS's quality requirements for imaging. Private plans often rely on accreditation programs to certify that their imaging providers meet quality standards.

Clinical diagnostic lab tests

In the proposed rule, CMS seeks input on requiring laboratories to submit the clinical results of tests that they perform on the claims they make for payment. Steps toward this new requirement should begin now.

Currently, the administrative data derived from claims can only indicate whether a particular test has been performed. For example, current administrative data can indicate whether a diabetic patients' hemoglobin A1c (HbA1c) level has been tested. By performing the test, the physician is adhering to the evidence base that indicates this test is important for diabetic patients. Conducting the test, however, is only means to an end: in this case, the goal is to lower patients' HbA1c levels to a healthy level. Though the process of conducting the test is necessary to determine whether control has been achieved, strong evidence shows that actually achieving the intermediate outcome of controlling the HbA1c level leads to the best ultimate outcomes, namely, decreased mortality and morbidity among patients with diabetes.

Many private sector performance measurement systems have moved away from measuring whether the test has been done to measuring whether control has been achieved. For example, the Integrated Healthcare Association's physician pay for performance program included measures for testing diabetic patients' HbA1c and low-density lipoprotein (LDL) in their first year and introduced measures of control of HbA1c and LDL in their second and subsequent years. The Bridges to Excellence physician recognition program also has indicators of both testing and control in its physician quality measurement program. Measures of HbA1c and LDL control are also included in Medicare's physician voluntary reporting program (PVRP).

Requiring labs to report clinical values would allow Medicare's quality measurement to evolve in three ways. First, gathering clinical data from the labs that perform the tests—rather than requiring physicians to collect and report the lab value data—would allow quality measurement efforts to include the substantial number of physicians who would be excluded from measurement because they do not or cannot collect and report clinical lab values. So far, only about 6,000 physicians have participated in Medicare's PVRP which requires lab values. Second, the measures themselves could evolve from process to intermediate outcomes, thus improving the measures by moving them closer toward the goal of measuring whether patients' health is better. Finally, other important measures of control for other clinical conditions—such as the serum albumin level of elders at risk for

Mark McClellan
Administrator
Page 7

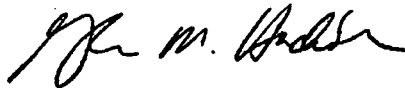
malnutrition or the hemoglobin levels for chemotherapy patients who use erythroid growth factors—could be added to the measure set without creating a new data burden on physicians. Reporting laboratory information as part of claims is not without burden. Industry representatives say that clinical and financial systems are often separated; it would take work to link them. It may be difficult to design fields to capture the variety of clinical lab results, including numeric results, codes, and narratives. However, because of the important role this information could play in the evolution of quality measurement, the changes needed to implement this new reporting function for clinical labs should be required as soon as possible.

Conclusion

MedPAC appreciates the opportunity to comment on the important policy proposals crafted by the Secretary and CMS. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact Mark Miller, MedPAC's Executive Director.

Sincerely,

A handwritten signature in black ink, appearing to read "Glenn M. Hackbarth".

Glenn M. Hackbarth, J.D.
Chairman

GMH/aw/w

Testimony of:
Robert A. Vito
Regional Inspector General for Evaluation and Inspections
Office of Inspector General, U.S. Department of Health and Human Services

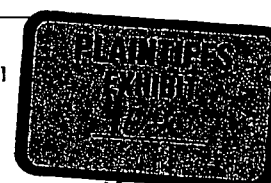
Good afternoon, Madam Chairman. I am Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia at the U.S. Department of Health and Human Services' Office of Inspector General (OIG). I appreciate the opportunity to appear before you today to discuss OIG's most recent work regarding Medicare Part B reimbursement for prescription drugs and the average sales prices (ASP) used to set this reimbursement.

In short, the new system appears to have lowered the previously inflated Part B reimbursement amounts and, in turn, reduced overall Medicare expenditures for prescription drugs. Even so, OIG's work has identified a small number of instances in which the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. We have also identified an issue with the method CMS uses to calculate reimbursement amounts.

FLAWS IN THE PREVIOUS REIMBURSEMENT SYSTEM

Prior to 2004, Medicare Part B reimbursed for most covered drugs based on the lower of either the billed amount or 95 percent of the average wholesale price (AWP) as published in national pricing compendia. The AWP is not defined by law or regulation, nor is it typically based on actual sales prices. As numerous reports by OIG and the Government Accountability Office have illustrated, the AWP-based reimbursement amounts for most covered drugs were significantly higher than the prices that drug manufacturers, wholesalers, and other similar entities actually charged the physicians and suppliers who purchase these drugs. Consequently, under this flawed system, the Medicare program and its beneficiaries were overpaying by hundreds of millions of dollars per year for prescription drugs.

To help align reimbursement amounts with actual acquisition costs, Congress included in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions to reform Part B drug reimbursement. The MMA specified that reimbursement amounts for most outpatient prescription drugs furnished in 2004 be set at 85 percent of the AWP, until a new methodology could be implemented on January 1, 2005. This new methodology based reimbursement amounts on manufacturer-reported ASPs rather than AWP. Unlike the AWP, an ASP is defined by statute and based on actual sales transactions. The MMA defines an ASP as a manufacturer's sales of a drug to all nonexempt purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter. The ASP is net of any price concessions such as volume, prompt pay, and cash discounts; free goods contingent on purchase requirements; chargebacks; and rebates other than those paid



under the Medicaid drug rebate program.^{1,2} Under this new methodology, Medicare reimbursement for most Part B drugs is set at 106 percent of the drugs' volume-weighted ASPs.³

IMPACT OF ASPs ON MEDICARE REIMBURSEMENT

The Congressional Budget Office estimated that the changes enacted by the MMA would save Medicare almost \$16 billion over 10 years by reducing excessive Medicare reimbursement amounts for Part B-covered drugs. Recent data on Medicare reimbursement and expenditures provide evidence confirming that the ASP-based reimbursement system has substantially lowered reimbursement amounts for numerous drugs. For about one-quarter of the drugs covered under Part B, Medicare reimbursement amounts have been reduced by at least 50 percent when compared to pre-MMA levels. For example, in 2003⁴ (when reimbursement was set at 95 percent of the AWP), Medicare paid almost \$120 for a month's supply of the inhalation drug albuterol; today, Medicare pays \$20.⁵ For the cancer drug Zoladex, Medicare paid almost \$450 per dose in 2003; Medicare currently pays \$196 per dose.

The reductions in the reimbursement amounts for individual drugs have had a substantial effect on overall Part B expenditures. Before the MMA was enacted, CMS data indicated that Medicare expenditures for Part B drugs had increased by at least 20 percent annually every year since 1994. By 2004, Medicare was paying almost \$11 billion for covered drugs, up from \$4 billion just 6 years earlier. Due to changes made by the MMA, this trend has reversed, with Medicare Part B spending close to \$1 billion less on covered drugs in 2005 than in 2004. This decrease occurred despite rising utilization for the drugs.

OIG WORK INVOLVING MEDICARE PART B DRUGS

Prior to the passage of the MMA, OIG's primary role in Medicare drug pricing involved identifying and reporting on flaws in the AWP-based system that left the program vulnerable to fraud, waste, and abuse. In more than a dozen reports, we repeatedly found that Medicare paid too much for prescription drugs due to inflated AWPs. In addition, working with our many law-enforcement partners, we assisted in investigations of pricing issues that resulted in significant civil and criminal settlements.

¹ Section 1847A(c) of the Social Security Act, as added by the MMA.

² Pursuant to section 1847A(c)(2) of the Social Security Act, sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" for Medicaid drug rebate purposes.

³ Although manufacturers submit an ASP and sales volume for each individual drug product they sell, CMS does not establish a reimbursement rate for each specific drug product. CMS uses ASP data for individual drug products to calculate an overall ASP for the procedure code. The ASP for an individual drug product is weighted by the amount of that drug sold during the quarter. This means that the ASP for a drug with a high volume of sales should have greater influence on the reimbursement amount for a procedure code than an ASP for a drug with a low volume of sales.

⁴ All data and methods described in the testimony refer to calendar years.

⁵ These figures relate only to reimbursement for the drugs themselves. They do not include the dispensing fees paid to the supplier.

The MMA established two mandates for OIG that changed and expanded our role in monitoring Medicare drug pricing. First, the MMA mandated that OIG conduct a study on the adequacy of ASP-based reimbursement amounts for certain cancer drugs. Second, the MMA required OIG to perform an ongoing monitoring function that compares ASPs to other pricing points. As discussed below, we have recently completed studies that address both of these mandates.

OIG WORK REQUIRED BY THE MMA

Adequacy of ASP-Based Reimbursement for Certain Cancer Drugs

The MMA required that OIG conduct a study on the ability of physician practices of different sizes in the specialties of hematology, hematology/oncology, and medical oncology to obtain drugs and biologicals at 106 percent of the ASP. This requirement responded to concerns that the new reimbursement amounts based on ASPs may be lower than the drug acquisition costs for physicians in these specialties. OIG completed this study in September 2005.⁶

We compared the average prices paid by physicians for drugs represented by 39 procedure codes to Medicare reimbursement amounts and concluded that physician practices in the three specialties could generally purchase drugs for the treatment of cancer patients at less than the MMA-established reimbursement rates (i.e., 106 percent of the ASP). Overall, the report found that the average prices paid for 35 of the 39 drugs under review were less than the Medicare reimbursement amounts. Larger physician practices purchased drugs at greater discounts (i.e., at least 15 percent below Medicare reimbursement) for more drugs than smaller practices. In addition, we also estimated that for 35 of the 39 codes, physician practices could purchase drugs for less than the reimbursement amounts during at least half of the months reviewed.

OIG Comparisons of ASPs to Other Pricing Points

The MMA also mandated that OIG conduct studies that determine whether the ASP exceeds certain other prices. Specifically, the MMA required OIG to compare manufacturer-reported ASPs to both average manufacturer prices (AMP)⁷ and widely available market prices (WAMP).⁸ In certain situations where the ASP of a drug exceeds the AMP or the WAMP by a certain threshold, the MMA gives the Secretary the authority to reduce the reimbursement amount for the drug to either 103 percent of the AMP or 100 percent of the WAMP. Currently, the threshold amount is 5 percent, although the Secretary has the authority to raise or lower this percentage in the future.

⁶ "Adequacy of Medicare Part B Drug Reimbursement to Physician Practices for the Treatment of Cancer Patients." A-06-05-00024.

⁷ AMPs, also reported by drug manufacturers to CMS, are used in the determination of rebates in the Medicaid program. As defined in section 1927(k)(1) of the Social Security Act, the AMP is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, minus customary prompt pay discounts.

⁸ Section 1847A(d)(5) of the Social Security Act generally defines widely available market price to be the price that a prudent physician or supplier would pay for the drug, net of any routinely available price concessions.

- Comparisons of ASPs to AMPs. OIG completed the first of its studies comparing ASPs to AMPs and issued a report earlier this year.⁹ We found that in the third quarter of 2004, 51 of the 364 procedure codes (14 percent) included in this review had an ASP that exceeded the AMP by at least 5 percent. If reimbursement amounts for these 51 codes had been lowered to 103 percent of the AMP, Medicare expenditures would have been reduced by an estimated \$164 million in 2005.

In response, CMS stated that the information in the report was helpful in its continuing efforts to monitor payment adequacy under the ASP methodology. However, CMS noted that OIG's review was conducted using data submitted during the initial implementation phase of the ASP methodology. Although CMS acknowledged the Secretary's authority to adjust ASP payment limits when certain conditions are met, it believed that other factors should be considered, including the timing and frequency of pricing comparisons, stabilization of ASP reporting, the effective date and duration of rate substitution, and the accuracy of ASP and AMP data.

In June 2006, OIG released a second report comparing ASPs to AMPs.¹⁰ We found that for 46 of the 341 procedure codes (13 percent) included in this review, ASPs exceeded AMPs by at least 5 percent in the fourth quarter of 2005.¹¹ Twenty of these codes were identified in OIG's previous report as having ASPs that exceeded AMPs by at least 5 percent in the third quarter of 2004. If reimbursement amounts for the 46 codes had been based on 103 percent of the AMP, we estimate that Medicare expenditures would have been reduced by \$64 million in one year.

- Comparison of ASPs to WAMPs. In addition to the comparisons of ASPs and AMPs, OIG released a report comparing ASPs to WAMPs in June 2006.¹² For this analysis, we specifically selected a purposive sample of nine procedure codes for which we suspected that the ASP might exceed the WAMP by at least 5 percent. The purposive sample was based on the results of the September 2005 OIG report on adequacy of reimbursement for cancer drugs.

We found that 5 of the 9 procedure codes included in this review met or surpassed the 5-percent threshold defined by the MMA. For these 5 codes, the ASPs exceeded the WAMPs by a range of 17 to 185 percent. We estimate that Medicare expenditures would be reduced by as much as \$67 million in 2006 if reimbursement amounts were lowered to the WAMPs for these 5 codes. In

⁹ "Monitoring Medicare Part B Drug Prices: A Comparison of Average Sales Prices to Average Manufacturer Prices." OEI-03-04-00430, May 2006.

¹⁰ "Comparison of Fourth Quarter 2005 Average Sales Prices to Average Manufacturer Prices: Impact on Medicare Reimbursement for the Second Quarter of 2006." OEI-03-06-00370.

¹¹ Fourth-quarter 2005 ASPs are used to set second-quarter 2006 reimbursement amounts.

¹² "A Comparison of Average Sales Prices to Widely Available Market Prices: Fourth Quarter 2005." OEI-03-05-00340.

addition, the prices that physicians pay for these drugs may be even lower than the WAMPs that were calculated, as all of the responding distributors offered price discounts to physician customers that were not reflected in the calculation of WAMPs.¹³

ADDITIONAL OIG WORK INVOLVING ASP

CMS's Calculation of ASPs

For the most part, the Medicare Part B reimbursement amount for a drug is now based on a volume-weighted ASP that CMS derives from the underlying ASPs for individual drug products reported by manufacturers. In the process of conducting the mandated price comparisons, we identified a problem with the method CMS uses to calculate volume-weighted ASPs. We alerted CMS to the problems with its calculation and issued a report on this subject in February 2006.¹⁴ We found that CMS's method for calculating a volume-weighted ASP is mathematically flawed because CMS does not consistently weight the number of units of a drug that were sold throughout its equation. As a result, many procedure codes have a reimbursement amount that is higher or lower than the amount that would have been calculated if the weighting were applied consistently.

According to OIG's analysis of prices published in the first quarter of 2005, the flawed calculation caused 46 percent of procedure codes to be reimbursed at amounts that were higher than they should have been, resulting in an estimated \$115 million in excessive Medicare reimbursements in 2005. For 13 percent of procedure codes, CMS's reimbursement amount was lower than it should have been, representing an estimated \$5 million loss to providers in 2005. The flawed calculation did not affect reimbursement amounts for the remaining 41 percent of procedure codes. OIG recommended that CMS change its calculation of volume-weighted ASPs. Although CMS stated that it may consider altering the ASP methodology in the future, the agency has yet to make any changes to its calculation of volume-weighted ASPs.

Drug Manufacturers' Calculations of ASPs

OIG is currently auditing eight drug manufacturers to evaluate their methodologies for calculating ASPs for individual drug products. Several more audits are planned in the near future.

Adequacy of Reimbursement for Intravenous Immune Globulin

This Subcommittee and the House Committee on Energy and Commerce Subcommittee on Health requested that OIG evaluate the current state of pricing and supply for one specific drug, intravenous immune globulin (IVIG). Patient advocacy groups and physicians have repeatedly expressed concerns that, under the ASP-based reimbursement methodology, the cost for physicians to acquire IVIG exceeds Medicare's reimbursement

¹³ The most common type of price discount offered to physician customers was a prompt pay discount. Three of the five companies that responded to our request for information offered this type of incentive, with percentage discounts ranging from 1 to 3 percent, depending on the time of payment.

¹⁴ "Calculation of Volume-Weighted Average Sales Price for Medicare Part B Prescription Drugs." OEI-03-05-00310.

amount. OIG's work in this area is ongoing. A final report that addresses Medicare reimbursement for IVIG, provides perspectives on the supply and distribution of this unique product, and makes any recommendations that are warranted will be issued in the near future.

Dispensing Fees for Inhalation Drugs

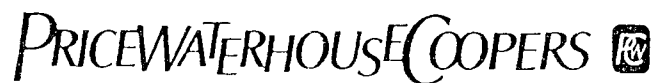
In tandem with the reimbursement reductions resulting from the MMA, CMS raised the dispensing fee paid by Medicare in 2005 for inhalation drugs from \$5 to an interim amount of \$57 for a 30-day drug supply. It did so based in large part on industry statements claiming that beneficiaries receive numerous, important services from their suppliers. Last year, OIG issued a report that reviewed the nature and extent of dispensing services that Medicare beneficiaries received from inhalation drug suppliers in 2003. OIG found that the most common service beneficiaries received was contact for drug refills. Few beneficiaries received more intensive services such as education, care plan revision, or a respiratory assessment, and 16 percent of beneficiaries received no services at all. The most common way beneficiaries received services was by telephone; only 1 in 10 beneficiaries received a home visit.

CONCLUSION

Prior to the passage of the MMA and the implementation of the new ASP-based methodology, Medicare reimbursed for many prescription drugs at prices that did not reflect actual acquisition costs for physicians and suppliers. Under the new system, there has been a substantial reduction in reimbursement amounts for many high-dollar products, causing the decade-long trend of increasing Part B expenditures for prescription drugs to reverse. Building on OIG's existing work that identified weaknesses in the old system, we have responded to new mandates under the MMA by taking on a more extensive role in helping to ensure the appropriateness of Medicare payments under the new methodology. As a result, OIG has already identified a few instances where the reported ASPs, and the resulting Medicare reimbursement amounts, may still be higher than certain other prices in the marketplace. In addition, OIG has undertaken nonmandated audits and evaluations of issues that we have identified as important to ensuring the integrity of Medicare Part B drug payments, such as the methodology used by CMS to calculate Medicare reimbursement amounts, and the methodologies used by drug manufacturers to calculate ASPs.

It appears that the new ASP methodology represents a marked improvement over the old AWP system. However, like any new reimbursement system, we realize that its implementation must be continually monitored to ensure that payment levels are appropriate. To this end, we are committed through our oversight work to provide CMS and Congress with timely information regarding ASPs and other drug reimbursement issues.

This concludes my testimony, and I welcome your questions.

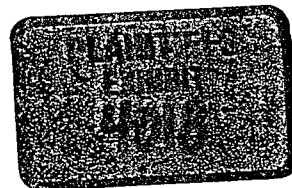


**Estimate of Savings to the Medicare Program from
Payment Changes for Covered Outpatient Drugs and Biologicals
Under the Medicare Modernization Act of 2003**

Prepared for:

The Community Oncology Alliance

April 27, 2005





Estimate of Savings to the Medicare Program for Payment Changes for Covered Outpatient Drugs and Biologicals

PricewaterhouseCoopers (PwC), as requested by the Community Oncology Alliance, estimated the savings to the Medicare program for covered outpatient drugs, including oncology drugs, based on changes in Part B reimbursement rates under the Medicare Modernization Act of 2003 (MMA). We estimate five-year savings (2004-2008) to Medicare for the payment changes to all drugs (MMA Sections 303 and 304) at about \$6.0 billion and the ten-year savings (2004-2013) at about \$19.3 billion. We also estimate the savings to the Medicare program based solely on payment changes for oncology drugs (Section 303). The five-year savings to the Medicare program is about \$4.0 billion and the ten-year savings is about \$13.0 billion.

These estimates are considerably higher than those estimated by the Congressional Budget Office (CBO) in 2003 at the time of enactment of the MMA. Specifically, CBO estimated five-year savings of \$3 billion and ten-year savings of \$11.5 billion to all specialties (Sections 303 and 304). For oncology drugs, CBO estimated five-year savings of \$0.9 billion and ten-year savings of \$4.2 billion.

Table 1.
Federal Budgetary Cost of the MMA Payment Changes to Outpatient Drugs and Biologicals
(Fiscal Years 2004-2013, in \$ billions)

Federal Outlays	2004	2005	2006	2007	2008	2004-2008	2004-2013
All Specialties	0.1	(0.8)	(1.5)	(1.8)	(2.0)	(6.0)	(19.3)
Sec 303: Oncology	0.1	(0.5)	(1.0)	(1.2)	(1.3)	(4.0)	(13.0)
Sec 304: Other Specialties	(0.0)	(0.3)	(0.5)	(0.6)	(0.6)	(2.0)	(6.3)

PricewaterhouseCoopers estimate. April 27, 2005.

Background

President Bush signed the Medicare Modernization Act (MMA) on December 8, 2003. This legislation, which affects almost every facet of Medicare, made significant changes in payment for Part B prescription drugs. Under Section 303 (oncology) and Section 304 (all other specialties) of the MMA, Part B drugs, which previously were reimbursed at 95 percent of Average Wholesale Price (AWP), were reimbursed at 85 percent of AWP in 2004 and then, in 2005, reimbursed at a new pricing system called, "Average Sales Price" (ASP). Specifically, Medicare reimbursement for prescription drugs dispensed by physicians will be set at ASP+6



percent. Finally, in 2006 and beyond, physicians will have a choice between providing the drugs and being reimbursed at ASP+6 percent or having these drugs provided by vendors selected in a competitive bidding process.

The MMA attempts to attenuate the impact on physicians in the following ways, neither of which fully offsets the major price reductions:

1. Physicians are given the option of having drugs provided by a supplier rather than purchased and sold by the physician. This option only assures that the least mark-up that can be received is zero rather than a negative amount. Physicians who administer drugs provided by a supplier would not be reimbursed for the prescription drug storage and other pharmacy-like services.
2. The payments for drug administration services are increased. Those extra payments, however, will replace only a fraction of the loss in prescription drug payments.

The implications of these changes for physicians and patients are significant. The economic incentives to provide prescription drugs are significantly reduced and the relative rewards and risks for the various prescription drugs as well as non-drug treatments are altered. This reduction in Medicare reimbursement is likely to result in an evaluation by physicians of their ability to continue to provide treatment to all or a sub-segment of Medicare beneficiaries.

PwC reviewed and updated the 2003 Congressional Budget Office's (CBO) estimate of the impact of these changes in reimbursement for prescription drugs and related services on total reimbursement to physicians, especially oncologists.¹ CBO's estimate in 2003 was based on their best information at that time, which did not include any specific information on ASP. We are able to update the CBO estimate by using ASP information for 2005.

Methodology

The following discussion provides the details and methodology behind the PwC budget estimate.

Impact of the MMA on Medicare Part B Spending

PwC estimated that Part B spending on prescription drugs and related services, before enactment of the MMA, would have been about \$10.8 billion for 2004. We assumed that spending would have grown at 8.7 percent on average each year in the absence of the MMA.

¹ Congressional Budget Office. *H.R.1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. November 20, 2003.



At this rate of growth, Part B drug spending would have been about \$22.8 billion in 2013. Medicare Part B drug spending has three components—prescription drugs, physician fees, and other allowable spending. The 2004 spending, prior to the enactment of the MMA, for prescription drugs was about \$6.5 billion, \$4.0 billion for fee schedule spending, and \$0.3 billion for other allowable spending.

2004

In 2004, drugs were paid at 85 percent of AWP under the MMA compared to 95 percent of AWP that would have been paid in the absence of the MMA. To calculate the spending after the change in drug pricing, we took the drug portion of the baseline and applied the 85 percent in place of the previous 95 percent for branded drugs. In addition to drug pricing changes, the MMA also increased the physician fees for drug administration covered under Part B by about 14 percent in 2004. We applied this percent to the portion of spending from fees. There are no stated changes to the other allowable spending, so there were no changes to this amount.

The gross savings from the MMA changes, before behavioral offsets, was about \$105 million (the difference between \$685 million in savings from reduced prescription drug reimbursement and \$580 million in costs from higher physician fees). We then applied a behavioral offset of 30 percent to the drug savings and it resulted in an additional cost of \$205 million (that is, 30 percent of the \$685 million in savings from prescription drug reimbursement cuts).² After accounting for this behavioral offset, the net impact of the MMA on Part B drug-related payments in 2004 resulted in an increase in total federal costs of about \$100 million in Calendar Year 2004. The net cost on a fiscal-year basis would be about \$65 million.

2005

In 2005, the MMA set reimbursement for Part B drugs at ASP+6 percent. Based on new information from the Centers for Medicare and Medicaid Services (CMS), we assumed that the most recent ASP+6 percent pricing system reduces drug payments by about 31 percent.³ The increase in the drug administration fee is 3 percent over what it would have been in the absence of the MMA—but less than the 32 percent increase in 2004. We estimated the effect of the total fee schedule changes would increase fees by about 11 percent. There are no stated

² The behavioral offset accounts for additional Medicare spending once the price of drugs decreases. CBO assumed 30 percent offset in 2004 for drugs only.

³ CBO's 2003 estimate appears to be based on the assumption that ASP+6 percent would be about 85 percent of AWP.



changes to the other allowable spending. The fiscal year savings would be about \$0.8 billion after accounting for behavioral offsets.⁴

2006 and Beyond

In 2006 and thereafter, physicians will have a choice of whether they purchase drugs and receive the ASP pricing system or have the drugs distributed by vendors selected through a competitive bidding process. We have assumed that all physicians will be reimbursed by the ASP pricing system. This is a conservative estimate of potential savings because our assumption is that Medicare will pay ASP+6 percent rather than the lower competitive amount. Based on this assumption, the reduction in drug spending in 2006, and thereafter, will be the same as in 2005, or about 31 percent. The increase in the drug administration fee is phased out in 2006. We estimate the fiscal year savings would be about \$1.5 billion after accounting for behavioral offsets.

2004-2013

We estimate the total savings over the five-year savings (2004-2008) to the Medicare program would be about \$6.0 billion and \$19.3 billion for the ten-year savings (2004-2013).⁵

Impact of the MMA on Oncology Medicare Part B Spending

Oncology drugs account for about 54 percent of total Part B spending on prescription drugs and related services. We estimated the Part B spending for oncology drugs and related services to be about \$5.8 billion in 2004 in the absence of the MMA. The 2004 breakdown of oncology drug and related services (in the absence of the MMA) is estimated at \$4.6 billion for drug spending, \$1.1 billion for fee schedules, and \$0.1 billion for other allowable spending.

In 2004, drugs were paid at 85 percent of AWP under the MMA compared to 95 percent of AWP in the absence of the MMA. To calculate the spending after the change in drugs pricing, we took the drug portion of the baseline and applied the 85 percent in place of the previous 95 percent. In addition to drug pricing changes, the MMA also increased physician and drug administration fees by 45 percent (specifically, a 32 percent increase in drug administration

⁴ We used a 30 percent behavioral offset for all savings (drugs and fees) in 2005 and beyond. This is a conservative estimate (in the sense of potentially understating savings) and is consistent with CMS. CBO used a 15 percent behavioral offset for 2005 and beyond.

⁵ Our savings estimate does not include indirect effects on the federal outlays for Medicare Part B premium, Medicare Advantage, and the Medicaid program. CBO included offsets in their estimate of the MMA but all the offsets were folded into similar offsets from dozens of other programs and reported together. Incorporating the offsets would reduce total savings by about 4 percent.



fees and other stated changes in Section 303). We applied this percent to the portion of spending from fees.⁶ There are no stated changes to the other allowable spending.

The savings from these changes was about \$14 million (the difference between the spending after changes and the baseline spending). We also applied a behavioral offset of 30 percent to the drug savings and it resulted in an additional cost of \$147 million. The total cost increase of the Part B changes to reimbursement is about \$133 million. This amount is based on the calendar year. The total costs after accounting for calendar versus fiscal year differences and collection lags is about \$87 million.

In 2005, we estimate that the new ASP+6 percent pricing system reduces oncology drug payments by about 29 percent, based on new information from CMS.⁷ We estimated the effect of the fee schedule pricing will increase fees by about 31 percent, partially due to the drug administration fee changes. The total savings (the difference between the spending after changes and the baseline) would be about \$0.5 billion, after accounting for the behavioral offsets and fiscal year conversions.

In 2006 and thereafter, reduction in drug spending is estimated at 29 percent. The fiscal year savings is estimated at \$1.0 billion after accounting for behavioral offsets. We estimate the total savings over the five-year savings (2004-2008) to the Medicare program would be about \$4.0 billion and the ten-year savings (2004-2013) would be about \$13.0 billion.

Policy Option: Extending the Oncology Demonstration Program through 2013

CMS is conducting a one-year demonstration program for oncologists in 2005. Specifically, CMS will provide oncologists a payment of \$130 for providing specific services to patients and reporting specific quality data. CMS has estimated that this would cost \$300 million in 2005. If CMS were to extend the demonstration project and provide \$300 million to oncologists each year during the period, 2006-2013, the savings from Section 303 would be about \$2.9 billion for five years and \$10.4 for ten years as compared to CBO's estimate of the MMA savings of \$0.9 billion and \$4.2 billion for five and ten years, respectively. If the demonstration amount were grown each year to reflect Part B spending growth, the savings to Medicare would be about \$2.7 billion for five years and \$10.0 billion for ten years.

⁶ Physicians also received a 1.5 percent update in fees for 2004 and 2005. The increase, however, was part of Section 601 and is not included in this estimate.

⁷ Based on the top 16 oncology drugs, which represent about 75 percent of payments to oncologists, the average ASP for the first and second quarter of 2005 is about 71 percent of 95 percent of AWP. The drug pricing information was downloaded from: <http://www.cms.hhs.gov/providers/drugs/asp.asp>.



**Estimate of Savings to the Medicare Program from
Payment Changes for Covered Outpatient Drugs and Biologicals
Under the Medicare Modernization Act of 2003**

An Update

Prepared for:

The Community Oncology Alliance

September 20, 2005



Estimate of Savings to the Medicare Program for Payment Changes for Covered Outpatient Drugs and Biologicals

In April, PricewaterhouseCoopers (PwC), as requested by the Community Oncology Alliance, estimated the savings to the Medicare program for covered outpatient oncology drugs based on changes in Part B reimbursement rates under the Medicare Modernization Act of 2003 (MMA). Based on April information, we estimated five-year savings to the Medicare program at \$4.0 billion and the ten-year savings at \$13.0 billion.¹

We recently updated our April estimate and based it on recent ASP information from the Centers for Medicare and Medicaid Services (CMS), estimates of Part B spending under the MMA from CMS, and other changes in assumptions based on more recent information. In our April estimate, we stated that the ASP+6 percent pricing system reduces drug payments by about 31 percent but recent information from CMS suggests, this reduction is closer to 30 percent. More significantly, the most recent CMS estimate for Part B oncology drug spending is about \$5.0 billion compared to our April estimate of \$3.6 billion.² Based on these CMS estimates of higher drug spending, we now assume the oncology drug growth rate to be about 14.5 percent, compared to 10 percent in our April estimate. These changes resulted in an estimate with greater savings to the Medicare program—\$4.1 billion and \$15.7 billion for the 2004-2008 and 2004-2013 periods, respectively.

Table 1.
Update Federal Budgetary Cost of the MMA Payment Changes to
Outpatient Drugs and Biologicals
(Fiscal Years 2004-2013, in \$ billions)

Federal Outlays	2004	2005	2006	2007	2008	2004-2008	2004-2013
PwC's April Estimate	\$0.1	(\$0.5)	(\$1.0)	(\$1.2)	(\$1.3)	(\$4.0)	(\$13.0)
Updated Estimate	\$0.1	(\$0.4)	(\$1.0)	(\$1.3)	(\$1.5)	(\$4.1)	(\$15.7)

PricewaterhouseCoopers estimate, September 2005.

¹ See PricewaterhouseCoopers. Health-Policy Economics' "Estimate of Savings to the Medicare Program from Payment Changes for Covered Outpatient Drugs and Biologicals Under the Medicare Modernization Act of 2003." April 2005.

² Adapted from the Federal Register's "Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006. Proposed Rule," August 8, 2005.



Impact of the MMA on Oncology Medicare Part B Spending

Oncology drugs account for about 69 percent of total Part B spending on prescription drugs and related services. We estimated the Part B spending for oncology drugs and related services to be about \$7.3 billion in 2005. The 2005 breakdown of oncology drug and related services is estimated at \$5.0 billion for drug spending, \$2.0 billion for fee schedules, and \$0.3 billion for other allowable spending.

In 2005, we estimate that the new ASP+6 percent pricing system reduces oncology drug payments by about 30 percent, based on new information from CMS. In addition, we updated the growth rate for oncology drugs from 10 percent in our April estimate to 14.5 percent based on higher drug spending and utilization estimates from CMS. We also estimated the effect of the fee schedule pricing will increase fees by about 31 percent, partially due to the drug administration fee changes. The total savings (the difference between the spending after changes and the baseline) would be about \$0.4 billion, after accounting for the behavioral offsets and fiscal year conversions.

In 2006 and thereafter, reduction in drug spending is estimated at 30 percent. The fiscal year savings is estimated at \$1.0 billion after accounting for behavioral offsets. We estimate the total savings over the five-year period (2004-2008) to the Medicare program would be about \$4.1 billion and the ten-year savings (2004-2013) would be about \$15.7 billion.

Comparison to the Congressional Budget Office's Estimate

CBO estimated the savings from Section 303 of the MMA at \$0.9 billion for the 2004-2008 period and \$4.2 billion for the 2004-2013 period. Based on the above analysis, we estimated that savings under the MMA would be \$4.1 billion and \$15.7 billion, respectively. This is nearly four times the original \$4.2 billion in savings that CBO estimated for Section 303 of the MMA.

House Committee on Ways and Means

Statement of Frederick M. Schnell, M.D., President, Community Oncology Alliance

Testimony Before the Subcommittee on Health
of the House Committee on Ways and Means

July 13, 2006

Medicare Part B reimbursement for cancer care is insufficient in 2006. The implications of insufficient reimbursement are that community cancer clinics report sending more patients to the hospital for treatment, closing satellite facilities and practices, reducing staff, and being pressured to factor economic decisions into the cancer treatment plan in order for clinics to continue treating patients. Additionally, clinics report considering dropping out of the Medicare program. Already, in 2006, there are reports about access problems from community cancer clinics in over 37 states.

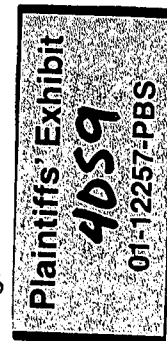
The fundamental problem with Medicare Part B reimbursement in 2006 is that drug administration reimbursement has decreased by over 20% since 2004 while drug reimbursement has decreased by over 30%. So, during a time period when underlying medical costs are increasing approximately 4% per year, reimbursement for both essential services and drugs required to treat seniors covered by Medicare Part B continues to decrease. Relating to services reimbursement, certain services such as cancer treatment planning and pharmacy facilities are not reimbursed. Relating to drug reimbursement, Medicare reimbursement of Average Sales Price (ASP) + 6% appears in cases to cover drug acquisition costs. However, reimbursement for most cancer drugs is actually less than cost when including the realities of pharmacy facilities, prompt pay wholesaler discounts, bad debt, and manufacturer price increases. Community cancer clinics, where 84% of the cancer patients in the United States are treated, cannot continue to operate in an environment where costs are exceeding reimbursement.

The specific problems with Medicare reimbursement are three-fold.

Problem #1: Medicare payment for drug administration is inadequate and is decreasing.

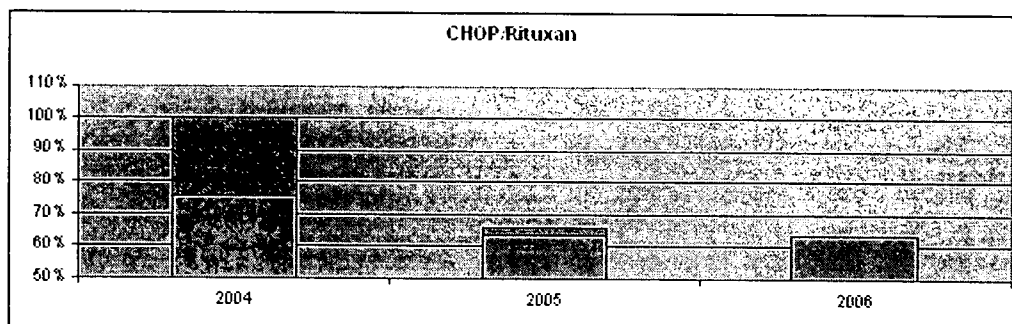
The Medicare Modernization Act (MMA) increased drug administration payments by 110% starting in 2004. The MMA also created a lump-sum transition increase of 32% that further raised drug administration payments in 2004. This transition increase decreased to 3% in 2005 and was eliminated in 2006. The purpose of this transition increase was for the Centers for Medicare & Medicaid Services (CMS) to ascertain the adequacy of existing payment codes and to create new codes for un-reimbursed services, such as treatment planning.

Unfortunately, in 2004 no new major payment codes were created by CMS for 2005; only temporary "G codes" were created. Instead, CMS developed a chemotherapy demonstration project for 2005 that retained at least \$300 million in Medicare funding for cancer care. This stopgap funding, along with the 3% transition fee and averted cut in the physician fee schedule, minimized any impact on community oncology during 2005. However, the chemotherapy demonstration project and transition increase both expired at the end of 2005, which resulted in lower Medicare reimbursement in 2006. Additionally, CMS replaced the temporary "G codes" with new codes at a lower relative value unit (RVU) rate and with no clear "cross walk" (i.e., translation) from the "G codes." This resulted in an additional decrease in drug administration reimbursement. Exhibit A shows a coding analysis performed by expert coders from around the country. Analyzing some commonly used cancer treatment regimens, it is clear that



reimbursement for drug administration only (this analysis excludes drug reimbursement) on a treatment-by-treatment basis has decreased substantially from 2004 to 2006. This decrease is estimated to be in excess of 20% overall.

The graph below illustrates the components of declining drug administration for the CHOP/Rituxan treatment regimen presented in Exhibit A. The purple portion of the bar in 2004 and 2005 illustrates the impact of the transition increases—32% in 2004 and 3% in 2005. The blue portion represents the underlying RVU-based payment.



It is illogical that Medicare drug administration reimbursement has decreased over 20% from 2004 to 2006 in light of the fact that medical human resource and supply costs have actually increased by approximately 4% per year during this period. It must be noted this has occurred when drug reimbursement has decreased by over 30% with the change from the prior AWP system to the new ASP-based reimbursement system.

Problem #2: Certain essential cancer care services and costs are not reimbursed.

The prior AWP-based reimbursement system resulted in drug reimbursement overpayments that subsidized essential cancer services that were either under-reimbursed or not reimbursed. Under the ASP-based system there is neither a subsidy nor a direct or indirect reimbursement for certain essential services. For example, cancer treatment planning is not reimbursed as part of any existing Medicare payment mechanism. It is ironic that radiation oncology treatment planning, which is typically part of the overall cancer treatment plan, is reimbursed by Medicare, whereas medical oncology treatment planning is not reimbursed. As another example, all of the direct drug costs of a pharmacy are not reimbursed. These include storage, inventory, pharmacy operations, and waste disposal. In light of increasing regulations dealing with chemotherapy and other toxic drug handling, the costs of maintaining a pharmacy are increasing. However, these costs are not reimbursed directly or indirectly.

Although some argue that many costs are “bundled” in the drug administration payment codes, there is no evidence that this is true or that these costs are appropriately covered by payment codes. In fact, the existing codes for drug administration have not been updated—even with the 2004 MMA 110% increase—to reflect the increasing costs of simply administering cancer drugs, much less cover any other facets of cancer treatment, such as treatment planning.

Problem #3: ASP + 6% may only barely cover drug acquisition costs. It does not cover all direct drug costs.

A clinic's total drug costs are comprised of drug acquisition costs, pharmacy costs, billing and overhead, and bad debt. Analyzing a clinic's drug acquisition costs in comparison to ASP + 6% reimbursement and

concluding that reimbursement covers cost is a faulty analysis, which is the problem with studies completed by the Office of the Inspector General (OIG) and the Government Accountability Office (GAO). The table below shows both OIG's estimated purchase price by drug (column a) along with the corresponding drug reimbursement rate (column b). If all of the patient's co-insurance was paid, most of the drug acquisition cost is covered by the reimbursement (column c). However, factoring in bad debt of 5.3% most of the drug acquisition costs are not covered by the reimbursement (column d). On a case-by-case basis, the impact of non-payment of the 20% co-insurance is substantial (column e). If you factor in bad debt and selected other direct drug costs, the result is a further under-reimbursement of drug costs.

Drugs	(a) OIG Estimated Average Purchase Price	(b) 4th Quarter Medicare Payment Rate	(c) If Total Amount Paid	(d) Bad Debt Factor of 5.30%	(e) If No Co-pay Collected	(f) Bad Debt Factor and Other Drug Costs
Carboplatin	16.24	35.25	19.01	17.14	11.96	14.67
Dexamethasone	0.05	0.11	0.06	0.05	0.04	0.05
Cisplatin	2.05	2.37	0.32	0.19	(0.15)	0.03
Vinorelbine	35.71	42.83	7.12	4.85	(1.46)	1.85
Dolasetron Mesylate	4.04	6.52	2.48	2.13	1.18	1.68
Cyclophosphamide	2.03	2.12	0.09	(0.02)	(0.33)	(0.17)
Epoetin Alfa	9.20	9.22	0.02	(0.47)	(1.82)	(1.11)
Filgrastim	245.46	279.57	34.11	19.29	(21.80)	(0.28)
Darbepoetin alfa	15.61	15.06	(0.55)	(1.35)	(3.58)	(2.40)
Fluorouracil	1.49	0.64	(0.85)	(0.88)	(0.98)	(0.93)
Leucovorin	1.16	1.32	0.16	0.09	(0.10)	(0.00)
Palonosetron hydrochloride	16.38	17.99	1.61	0.66	(1.99)	(0.60)
Granisetron hydrochloride	6.39	7.14	0.75	0.37	(0.68)	(0.13)
Vincristine	3.18	3.60	0.42	0.23	(0.30)	(0.02)
Pegfilgrastim	2,080.71	2,078.07	(2.64)	(112.78)	(418.25)	(258.24)
Etoposide	0.46	0.49	0.03	0.00	(0.07)	(0.03)
Docetaxel	280.71	293.64	12.93	(2.63)	(46.80)	(23.19)
Pamidronate disodium	56.50	40.63	(15.87)	(18.02)	(24.00)	(20.97)
Gemcitabine hydrochloride	111.40	115.89	4.49	(1.85)	(18.69)	(9.76)
Fludarabine	263.12	262.87	(0.25)	(14.18)	(52.02)	(32.58)
Bevacizumab	55.27	57.11	1.84	(1.19)	(9.58)	(5.18)
Zoledronic acid	192.95	200.03	7.08	(3.52)	(32.93)	(17.52)
Trastuzumab	51.80	54.39	2.59	(0.29)	(8.29)	(4.10)
Oxaliplatin	8.07	8.53	0.46	0.01	(1.25)	(0.59)
Irinotecan	123.00	126.92	3.92	(2.81)	(21.46)	(11.69)
Mitoxantrone	316.10	323.80	7.70	(9.46)	(57.06)	(32.13)
Doxorubicin J9001	353.30	364.53	11.23	(8.09)	(61.66)	(31.61)
Topotecan	730.88	763.80	32.92	(7.56)	(119.84)	(61.03)
Octreotide	84.40	87.31	2.91	(1.72)	(14.55)	(7.83)
Diphenhydramine	0.93	0.72	(0.21)	(0.25)	(0.36)	(0.30)
Sargramostim	21.44	21.87	0.43	(0.73)	(3.94)	(2.26)
Amifostine	414.00	439.31	25.31	2.03	(62.55)	(28.73)
IVIg non-lyophil	56.26	56.30	0.04	(2.94)	(11.22)	(6.88)
Fulvestrant	79.97	81.33	1.36	(2.95)	(14.91)	(8.64)
Rituxan	440.10	455.92	15.82	(8.34)	(76.36)	(40.26)
Paclitaxel	16.71	13.33	(3.38)	(4.09)	(6.06)	(5.02)
Leuprolide	279.34	224.42	(54.92)	(66.81)	(99.80)	(62.52)
Enoxaparin Sodium	6.45	5.45	(1.00)	(1.29)	(2.09)	(1.67)
Doxorubicin J9000	5.48	5.84	0.36	0.05	(0.81)	(0.26)

It is unreasonable to simply look at drug acquisition costs in isolation without considering all direct drug costs. The stated Medicare drug reimbursement rate is ASP + 6%. However, factoring in other costs, the effective real rate is ASP - 3.8%. These include the MMA-mandated inclusion of prompt payment discounts between the pharmaceutical manufacturer and the wholesaler into the ASP calculation; the impact of the lag between a manufacturer's price increase and inclusion in the drug reimbursement rates; and the bad debt factor.

Stated Medicare Drug Reimbursement Rate	ASP + 6%
Less Prompt Pay Discount	2.00%
Less Price Increase Lag	2.50%
Less Bad Debt	5.30%

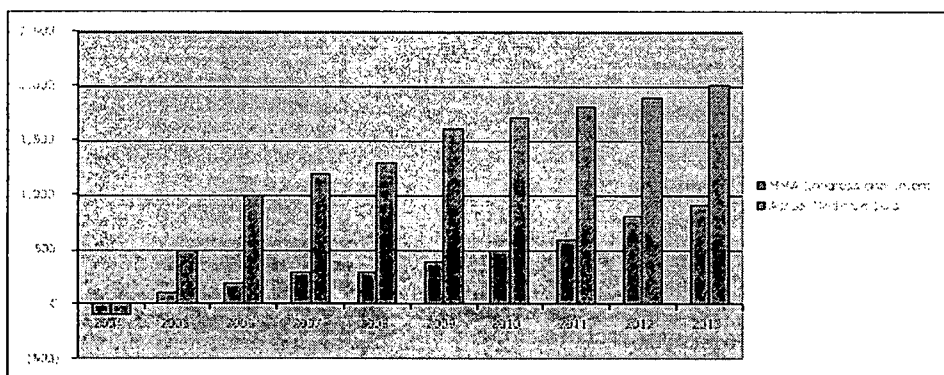
Effective Medicare Drug Reimbursement Rate**ASP – 3.8%**

Bad debt is a real cost incurred by community cancer clinics. COA estimates bad debt at 5.3% nationally. An estimated 12% of patients have no secondary co-insurance and in many states Medicaid—as the secondary insurer—does not cover the patient's co-insurance obligation. As the cost of cancer drugs escalate, patients are increasingly unable to cover co-insurance payments that can run over \$20,000. Bad debt is a reality of operating a community cancer clinic, yet it is ignored as a reality by CMS. Community cancer clinics historically have been willing to treat patients rather than turn them away or hand them over to a collection agency. However, community cancer clinics now are increasingly unable to subsidize cancer care for seniors covered by Medicare with no secondary insurance coverage.

This analysis does not include pharmacy costs. MedPAC estimated pharmacy costs at 26-28% of total drug costs in analyzing actual costs from outpatient facilities in Maryland. This analysis also does not include the cost of capital in purchasing very expensive cancer drugs or the costs of billing and overhead. Once again, under the AWP-based system these costs were part of drug reimbursement. However, under the ASP-based system only acquisition cost is reimbursed.

Some believe that the Competitive Acquisition Program (CAP) is a solution to drug reimbursement problems. However, CMS has struggled to find only one CAP vendor—after delaying the program because initially there were no vendors—and few if any community cancer clinics will trust an unproven, untested system to deliver the correct drugs on time to their patients. The CAP will create multiple patient inventories, risk treatment errors, and result in treatment delays. Additionally, the CAP will actually increase pharmacy and billing costs because of the procedures, tracking, and record keeping requirements. Analyzing the top reimbursed cancer drugs, COA estimates that Medicare will actually pay over 3% more for drugs to the CAP vendor than to community cancer clinics.

These three problems have resulted in Medicare now becoming the lowest payer for cancer care services. Medicare, with its considerable market clout, has set reimbursement rates artificially low for private payers to follow. In many cases, this is exactly what is happening.



The congressional intent of the MMA was to save Medicare \$4.2 billion from 2004-2013 by changing the reimbursement system for cancer care, according to the Congressional Budget Office in a letter dated November 20, 2003, to Chairman Thomas. Unfortunately, actual implementation by CMS is resulting in substantially more cuts to Medicare reimbursement for cancer care. Exhibit B is a report from PricewaterhouseCoopers that estimates the cuts to cancer care reimbursement to be \$13.8 billion, far in excess of the \$4.2 billion intended by Congress. The graph below shows this discrepancy in projected cuts (congressional intent) versus actual implementation by CMS. The reasons for this discrepancy are the three problems previously outlined in this document.

There is bipartisan recognition of this problem in both the House and the Senate. The entire cancer community supports solutions to this problem. There are currently three bills in the House addressing aspects of this overall problem, including one with over 70 sponsors that was introduced by Congressman Jim Ramstad, a member of the Ways and Means Subcommittee on Health. There is an identical Senate bill that was introduced by Senator Arlen Specter.

Some have suggested waiting to see more substantial patient access problems before fixing the problems with Medicare Part B reimbursement for cancer care. That is simply not acceptable because actual lives of Americans are already being negatively impacted. Furthermore, we risk dismantling a system of cancer care that has been built during the past 15-20 years. Rescuing the cancer care delivery system when it is too late will not be feasible because the damage will be done. Already, the incidence of cancer is increasing while the number of oncologists is flattening. Reimbursement problems should not be motivating older oncologists to retire, which is starting to happen, or discouraging new physicians from pursuing a specialty in oncology, which is also happening at the medical school and fellowship levels.

On behalf of community oncology, we ask the Congress to immediately fix the problems of insufficient Medicare reimbursement for cancer care by at least accomplishing the following:

- Eliminate "prompt payment" discounts from pharmaceutical manufacturers' calculation of ASP. Prompt payment discounts are financing discounts between the manufacturer and the wholesaler—these are not incentive purchasing discounts to community cancer clinics. Inclusion of these discounts in the ASP calculation artificially lowers Medicare drug reimbursement by approximately 2%.
- Immediately increase Medicare reimbursement for those drugs increased in price by the manufacturer. Community cancer clinics are currently subsidizing Medicare for all drug price increases for 6 months, on average.
- Create payment mechanisms for un-reimbursed services such as treatment planning and pharmacy facilities. Medicare reimbursement needs to more realistically cover the essential services provided to seniors by community cancer clinics.
- Reevaluate existing drug administration payment codes to restore adequate reimbursement that covers the costs of the materials and human resources required to administer drugs.
- Address the growing bad debt problem of Medicare patients without adequate secondary insurance.

An independent analysis of the plight facing community oncology appeared as a research article in the Journal of the National Comprehensive Cancer Network (*Surviving the Perfect Storm: An RVU-Based Model to Evaluate the Continuing Impact of MMA on the Practice of Oncology*; Volume 4, Number 1, January 2006). The authors write, "The emotional and financial pressures facing the medical oncologist in private practice are enormous, with no relief in sight. The complexity of managing private practice oncology rivals that of managing cancer care." "Will the planned changes in Medicare reimbursement, exacerbated by the loss of operational inefficient medical oncology practices, lead to irreparable changes in the oncology delivery system (e.g., access, availability, continuity, and quality)?" "Will the United States abrogate its leadership in clinical cancer care and default to a specialty of algorithm followers rather than algorithm creators? Are the unintended consequences of changes in regulation and reimbursement fully appreciated? And lastly and most importantly, what are the risks to the cancer patient resulting from the heuristic approach promulgated by regulators and legislators?"

Exhibit C presents a sample of quotes received from community cancer clinics across the country.

Exhibit A

HCPCS	Treatment Description	Total Dose Based 1.7 BSA/68 kg	Admin. Time	Administration Code Description	2003 and 2004 Administration Code	2006 Administration Code	Reimb 2004	Reimb 2006	2004 2006 Diff	2004- 2006% Diff
	CHOP/Rituxan	Non-Hodgkins Lymphoma								
J0000	Adriamycin 50mg/m ²	85mg	10 minutes	Sequential Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J0370	Vincristine 2mg	2mg	10 minutes	Sequential Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J0070	Cytosol 750mg/m ²	1275mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J09310	Rituxan 375mg/m ²	637.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96412 x 3	96417, 96415x2	\$144.00	\$182.57	\$17.67	12.10%
J2469	Aloxi 0.25mg	0.25mg	15 minutes	Short infusion	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	15 minutes	In same bag with Decadron	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	Folfox 6 + Avastin	Colorectal Cancer								
J0263	Oxaliplatin 100mg/m ²	170mg	2hrs	Initial IV Chemo Int + 1hr	96410/96412	96413, 96415	\$285.05	\$211.84	-\$73.21	-25.68%
J0640	Lecovirin 400mg/m ²	680mg	2hrs	Concurrent IV Infusion	Not coded	90768	\$0.00	\$24.63	\$24.63	
J0190	5FU 400mg/m ²	680mg	10 minutes	Sequential Chemo IVP	CCI edit	96411	\$0.00	\$70.87	\$70.87	
J0190	5FU 2400mg/m ²	4080mg	46hrs	Continuous Chemo IV int.	96414-50	96416	\$269.59	\$185.70	-\$83.89	-31.12%
J0035	Avastin 5mg/kg	340mg	1hr	Seq. IV Chemo Int.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J1100	Decadron 20mg	20mg	20 minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
	CarboTaxol Low Dose	Lung Cancer, Breast Cancer								
J0645	Carboplatin AUC 2	175mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0265	Taxol 80mg/m ²	136mg	1hr	Seq. IV Chemo Int.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J1100	Decadron 20mg	20mg	20 minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20 minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	CarboTaxol q3weeks	Lung Cancer, Breast Cancer								
J0645	Carboplatin AUC 5	425mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0265	Taxol 175mg/m ²	297.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96412 x 3	96417, 96415x2	\$144.00	\$182.57	\$17.67	12.10%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J1100	Decadron 20mg	20mg	20 minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20 minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	CarboTaxol q3weeks	Lung Cancer, Breast Cancer								
J0645	Carboplatin AUC 5	425mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0265	Taxol 175mg/m ²	297.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96412 x 3	96417, 96415x2	\$144.00	\$182.57	\$17.67	12.10%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J1100	Decadron 20mg	20mg	20 minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20 minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	CarboTaxol q3weeks	Lung Cancer, Breast Cancer								
J0645	Carboplatin AUC 5	425mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0265	Taxol 175mg/m ²	297.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96412 x 3	96417, 96415x2	\$144.00	\$182.57	\$17.67	12.10%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J1100	Decadron 20mg	20mg	20 minutes	Piggy-backed	Not coded	90768	\$0.00	\$24.63	\$24.63	
J2780	Zantac 50mg	50mg	20 minutes	Piggy-backed	Not coded	One per day	\$0.00	\$0.00	\$0.00	

Exhibit A (continued)

HCPCS	Treatment Description	Total Dose Based 1.7 BSA/68 kg	Administration Time	Administration Code Description	2004 Administration Code	2006 Administration Code	Reimb 2004	Reimb 2006	2004 2006 Diff	2004- 2006% Diff
	Dose Dense AC-Taxol	Breast Cancer								
J0000	Adriamycin 50mg/m ²	102mg	1-3 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J0070	Cytosol 600mg/m ²	1020mg	1hr	Initial Chemo int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0265	Taxol 175mg/m ²	297.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96412 x 3	96417, 96415x2	\$144.00	\$182.57	\$17.67	12.10%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	20 minutes	Seq. IV Infusion	Not coded	90767	\$0.00	\$42.46	\$42.46	
J2780	Zantac 50mg	50mg	20 minutes	Piggy backed with Decadron	Not coded	90768	\$0.00	\$24.63	\$24.63	
	TAC	Breast Cancer								
J0170	Taxolite 75mg/m ²	127.5mg	1 hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
J0000	Adriamycin 50mg/m ²	85mg	1-3 minutes	Seq. Chemo IVP	96408	96411	\$154.76	\$70.87	-\$83.89	-54.21%
J0070	Cytosol 600mg/m ²	850mg	1hr	Seq. Chemo Int.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J2469	Aloxi 0.25mg	0.25mg	10 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	10 minutes	In bag with Aloxi	Not coded	Not billed	\$0.00	\$0.00	\$0.00	
	Herceptin	Breast Cancer								
J0355	Herceptin 2mg/kg	136mg	1hr	Initial Chemo int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
	Taxol/Herceptin	Breast Cancer								
	Taxol 80mg/m ²	136mg	1hr	Initial IV Chemo Int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%
	Herceptin 2mg/kg	136mg	1hr	Seq. Chemo Int.	96412	96417	\$48.30	\$84.51	\$36.21	74.97%
J1200	Benadryl 50mg	50mg	15 minutes	Infusion now push	90780	90775	\$117.79	\$26.91	-\$90.88	-77.15%
J1100	Decadron 20mg	20mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	15 minutes	In bag with Benadryl	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	Taxol/Gemzar	Lung Cancer								
J0265	Taxol 175mg/m ²	297.5mg	3hrs	Seq. IV Chemo Int + 2hrs	96410/96412 x2	96417, 96415x2	\$313.95	\$182.57	-\$131.38	-48.22%
J0201	Gemzar 1250mg/m ²	2125mg	1hr	Initial IV Chemo int.	96412	96413	\$48.30	\$172.81	\$124.51	257.78%
J2469	Aloxi 0.25mg	0.25mg	5 minutes	Seq. IVP	Not paid	90775	\$0.00	\$26.91	\$26.91	
J1200	Benadryl 50mg	50mg	20 minutes	Seq. IV Infusion in one bag	90768	90768	\$117.79	\$24.63	-\$93.16	-79.09%
J1100	Decadron 20mg	20mg	20 minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
J2780	Zantac 50mg	50mg	20 minutes	Seq. IV Infusion in one bag	Not coded	One per day	\$0.00	\$0.00	\$0.00	
	Gemzar	Pancreatic Cancer								
J0201	Gemzar 1250mg/m ²	2125mg	1hr	Initial IV Chemo int.	96410	96413	\$217.35	\$172.81	-\$44.54	-20.46%

Exhibit B

President Bush signed the Medicare Modernization Act (MMA) on December 8, 2003. This legislation made significant changes in payment for Part B prescription drugs. Under Section 303 (oncology) of the MMA, Part B drugs, which previously were reimbursed at 95 percent of Average Wholesale Price (AWP), were reimbursed at 85 percent of AWP in 2004 and then, in 2005, reimbursed at a new pricing system called "Average Sales Price" (ASP), under which reimbursement was set at ASP+6 percent. Finally, in 2006 and beyond, physicians will have a choice between providing the drugs and being reimbursed at ASP+6 percent or having these drugs provided by vendors selected in a competitive bidding process.

PricewaterhouseCoopers (PwC), at the request of the Community Oncology Alliance, estimated savings to the Medicare program from changes in Part B reimbursement rates for covered outpatient oncology drugs and oncology-related services under the MMA. Based on the most recent information from the Medicare program, we estimate the savings of \$4.1 billion for the five-year period of 2004-2008 and \$13.7 billion for the ten-year period of 2004-2013 (as shown in Table 1 below).

These estimates are considerably higher than those estimated by the Congressional Budget Office (CBO) in 2003 at the time of enactment of the MMA. CBO estimated savings from Section 303 of the MMA at \$0.9 billion for the 2004-2008 period and \$4.2 billion for the 2004-2013 period, or about one-third PwC's estimate for the same period.[1] The differences in estimates are not surprising. CBO's 2003 estimate was based on their best information at that time, which did not include any specific information on ASP. In constructing our estimate, we had access to actual ASP information for 2005-2006 from the Centers for Medicare and Medicaid Services (CMS).[2]

Table 1.

**Federal Budgetary Cost of the MMA Payment Changes to
Oncology Outpatient Drugs and Biologicals
(Fiscal Years 2004-2013, in \$ billions)**

	2004	2005	2006	2007	2008	2004- 2008	2004- 2013
PwC's 2006 estimate	0.1	(0.5)	(1.0)	(1.3)	(1.4)	(4.1)	(13.7)
CBO's 2003 estimate	0.1	(0.1)	(0.2)	(0.3)	(0.3)	(0.9)	(4.2)
<i>Difference</i>	(0.0)	(0.4)	(0.8)	(0.9)	(1.1)	(3.2)	(9.5)
PricewaterhouseCoopers estimate, July 10, 2006.							

Methodology

In 2004, Part B oncology drugs were reimbursed at 85 percent of AWP under the MMA, compared to 95 percent of AWP in absence of the MMA. To calculate the spending after the change in drug pricing, we took the drug portion of the baseline and applied the 85 percent in place of the previous 95 percent for branded drugs. This reduced drug spending by \$0.5 billion. However, the reduction in drug payments was offset by the increase in payments to physician fee schedules under the MMA. Consequently, estimated payments in 2004 were virtually unchanged by the MMA.

In 2005, we estimated the new ASP+6 percent pricing system would reduce oncology drug payments by about 30 percent, based on new information from CMS. We applied this percentage to the baseline 2005 drug spending. This price reduction resulted in savings of \$1.8 billion in drug spending. In the meantime, physician fees spending was increased by \$0.4 billion. The combined impact of the MMA on oncology Part B spending would be gross savings of \$1.4 billion. These gross savings would result in fiscal year savings of \$0.5 billion to the Medicare program for 2005 after accounting for behavioral offsets, cost sharing, and conversion from calendar year to fiscal year.

Starting in 2006, physicians will have a choice of whether they purchase drugs and receive the ASP pricing system or have the drugs distributed by vendors selected through a competitive bidding process. We have assumed that all physicians will be reimbursed by the ASP pricing system. This is a conservative estimate of potential savings because our assumption is that Medicare would pay ASP+6 percent rather than the lower competitive amount. In 2006, the reduction in drug spending was estimated at about 35 percent, based on the first three quarters of ASP + 6 percent information. Total impact of the MMA on oncology Part B spending was estimated to be gross savings of \$2.2 billion, or \$1.0 billion in fiscal year savings to the Medicare program after accounting for behavioral offsets and cost sharing.

In 2007 and thereafter, the reduction in drug spending was assumed at 32 percent, the average of that of 2005 and 2006. We have also incorporated in our estimate proposed changes by CMS in work relative value units (RVUs) and practice expense (PE) RVUs affecting payments to physician services. These revisions are proposed to be effective starting January 1, 2007. Specifically, CMS estimated that the combined impact of work and PE RVUs changes would increase oncology physician fee schedules by 3 percent in 2007 (first year of PE transition) and by 2 percent in 2010 with full PE implementation.

We estimated the total savings over the five-year period (2004-2008) to the Medicare program would be about \$4.1 billion and the ten-year period (2004-2013) would be about \$13.7 billion, as reported in Table 1.

EXHIBIT C

"On an average we are sending 25-30 patients to the hospital a month for their chemotherapy treatment and growth factor support due to an overwhelming percentage of 20% coinsurance turning into bad debt. Facilities, however, are providing a very limited number of open chairs for patients which means patients are being delayed a week or two waiting on an open chair."

"We have only been able to send one patient to our local hospital due to the fact that they are refusing to accept Medicare, Medicaid, self pay, and managed care Medicaid patients based on the following factors: they are not set up for chemotherapy infusion; they do not have the staff needed; and lastly, they are not budgeted for the additional financial burden. We are still in negotiations with these hospitals and will let you know when/if we have a resolution."

"We have a practice that is unable to take on every referral. Two years ago we stopped doing second opinions, and rarely had to turn down new patients. This year we have turned down more new patients than ever in the history of our 15 years in this town--we no longer do self-referred patients, and cannot always take on new patients referred by physicians. Thus, we do not take any HMO's or any MediCal. Because chemotherapy is so expensive, we have stopped taking any dual eligibles. Many more patients have been hospitalized for chemo in our town than were three years ago, and that clearly is because the drugs are unaffordable, both to patients and doctors. If one of five Avastin patients fails to pay their 20%, our practice could go out of business."

We are looking toward closing one of our offices. We can no longer cover the overhead of the practice due to the inadequate payments of ASP+6%. The other reimbursement schedules are grossly inadequate. We have already cut staff. Medicare D for oncology patients is a catastrophe. Most cannot afford the co-pays on these very expensive drugs. They are priced out of effective medications such as the TK inhibitors, Revlamid, etc. THERE IS A NEW WRINKLE! Medicare is now not denying our claims but "PENDING" all claims for Rituxan, Aranesp, and Herceptin – thus they delay payment for three to four months. This has wiped out all of our money. We cannot purchase any more drugs! We will now be sending all patients to the hospital 10 miles away for chemotherapy. Does Medicare wish to eliminate the private practice of Medical Oncology?

"It seems that CMS excluded our specialty number 98 from yet another fix in their system. We still have not been paid from the first oversight which was the 2006 demonstration project, but to add insult to injury, a much worse problem has occurred and it seems that I cannot make any progress no matter what I do. Medicare has been pending all of our claims that include Aranesp, Procrit or Neulasta charges. They request medical records. They pend the entire claim to include any chemo drugs that may be included. We have not been paid this entire year for these drugs. I have stopped sending my claims for these services hoping to prevent this process and hold up on any additional claims."

"We did cost analyses on each chemo protocol based on each drug cost and overhead. This was done using our most common secondary reimbursements. Based on this, a list was sent to staff indicating which protocols were underwater. These are the treatments sent out. What was found was that without a secondary, in most cases with Medicare, we were underwater with some exceptions."

"We can't afford to treat patients that cannot pay their 20%. Right now 26 of 64 drugs we commonly give are underwater at 100% of Medicare. Also, the hospitals are seeing more and more patients in their outpatient units. We are in a high competition area, and a lot of the Oncologists in this area are sending patients to the hospital for treatment."

"When we treat patients without secondary coverage we put a financial burden on these patients. This is not the time to cause more stress; this is the time to allow the patient to heal. One example of financial stress is colon cancer; the treatment cost is \$8,000 every two weeks for 12 treatments. Patient responsibility is 20%, or \$1600 per treatment or \$3,200 per month. If they cannot afford secondary insurance, how can they afford \$3,200 per month for six months (\$19,200)? The clinic is to collect this amount. The clinic is not a collection agency. A pharmacist once said to me as I tried to call in a drug that cost \$1,200, why would I loan the patient a thousand dollars while the government decides to pay me? This \$19,200 is a loan that many times is paid in \$50 and \$100 installments. Maybe the government could loan the money to these patients so we can go back to assisting the patient in health care."

"We do see the Medicare only patients for OV and labs but refer them to the hospital for any treatment because most of our drugs will be in the red if we receive only 80% of the Medicare allowable. Most of our patients who only have Medicare do so because they cannot afford a secondary/supplemental – thus, cannot afford or will not pay the co-pay. We service western Kentucky which has a lot of the "working poor" who cannot even afford their employer's healthcare premiums and southern Illinois that is just poor with a very high percentage of Medicaid."

[1] Congressional Budget Office. *H.R.1 Medicare Prescription Drug, Improvement, and Modernization Act of 2003*. November 20, 2003.

[2] Our savings estimate does not include indirect effects on the federal outlays for the Medicare Part B premium, Medicare Advantage, and the Medicaid program. CBO did not show these offsets separately for individual sections of the MMA but, instead, folded together all the offsets of dozens of other programs and reported the overall offset.